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January 18, 2007

BY ELECTRONIC FILING

The Honorable Sue L. Robinson United States District Court 844 King Street Wilmington, DE 19801

Re: Boston Scientific Corp. and Boston Scientific Scimed, Inc. v. Conor Medsystems, Inc., 05-768-SLR (D. Del.)

Dear Chief Judge Robinson:

BSC respectfully submits this response to Conor's January 17, 2007 letter to the Court, which we believe misstates BSC's position and reliance on certain cases.

As stated in BSC's January 11, 2007 letter, BSC relies on *Ortho* for the proposition that uses of a patented invention for "obtaining foreign premarketing approval" are nonexempt. *Ortho Pharm. Corp. v. Smith*, Civ. A. No. 90-0242, 1990 WL 121353, *23 (E.D. Pa. Aug. 17, 1990), *aff'd*, 959 F.2d 936 (Fed. Cir. 1992). BSC relies on *Scripps* for the proposition that sales and other uses of a patented invention "unrelated to meeting FDA requirements" are "beyond the protection of § 271(e)(1)." *Scripps Clinic and Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1396 (N.D. Cal. 1987), *aff'd in part and rev'd in part on other grounds*, 927 F.2d 1565 (Fed. Cir. 1991). These aspects of *Ortho* and *Scripps* have not been reversed or overruled.

Given Conor's agreement to provide a 2006 update of its distributor documents, the only pending discovery issues are whether Conor should produce: (1) its documentation accompanying stent samples; and (2) its submissions to foreign regulatory authorities. These documents are necessary to determine whether the samples were used for nonexempt purposes and whether the submissions were based on clinical trials unrelated to FDA approval.

Contrary to Conor's suggestion, BSC does not base its arguments on dissemination of clinical data generated for the FDA. As a result, Conor's citation of *Telectronics* is inapposite. *See, e.g., Biogen, Inc. v. Shering AG*, 954 F. Supp. 391, 397 n.1 (D. Mass. 1996). Furthermore, BSC notes that after *Telectronics*, the Patent Act added the unauthorized offering for sale of a patented invention as another act of infringement under Section 271(a).

Respectfully submitted,

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